REMARKS

Prior to the present reply, claims 1-39 were pending. Due to a restriction requirement, claims 3-38 are withdrawn from consideration. In the final Office action mailed March 5, 2007, claims 1, 2, and 39 were examined. Claims 1, 2, and 39 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description required and further as failing to comply with the enablement requirement. Claims 1 and 2 are also rejected under 35 U.S.C. § 102(b) in view of the Affymetrix Human Genome U95A array (Affymetrix Product Catalog January 2001; hereafter "the Genone Array"). Each of these rejections is addressed below.

Interview Summary

Applicants' representative thanks Examiners Salmon and Goldberg for the helpful interview on August 9, 2007. During the interview, Applicants' representative presented proposed claim amendments in response to the rejections. The basis for the written description and enablement rejections was discussed, as was the application of the Genome Array in the § 102(b) rejection of the claims. Finally, the identity of genes constituting the class of "nuclear encoded mitochondrial energy metabolism genes" was discussed.

Claim amendments

Claim 1 has been amended to recite "nucleic acid molecules that encode polypeptides of complex I, II, III, IV, or V of the mitochondrial respiratory chain." Support for this change is found, for example, at page 22, lines 27-28 of the specification. Claim 1 has also been amended to recite "polypeptides being naturally coded for by a nuclear gene." Support for this change is found, for example, at page 18, lines 11-12. Claims 2 and 39 have been amended to correspond with language of amended claim 1. Withdrawn claims 3-38 have been canceled. New claims 40 and 41 have been added. These claims recite that the array consists of at least 10 or 25 nucleic acid molecules, respectively. Support for these claims is found for example, at page 18, line 27 through page 19, line 2. No new matter has been added by these amendments.

Rejections under 35 U.S.C. § 112, first paragraph, written description and enablement

In rejecting claims 1, 2, and 39 for lack of written description and enablement, the Office asserts that the specification fails to define what is encompassed by the term nuclear encoded mitochondrial energy metabolism nucleic acid molecules because the specification does not describe these genes in a way in which the ordinary artisan would know which portions of the nucleic acid retain a specific biological activity. Applicants respectfully disagree. In the context the presently claimed invention, it is not necessary for the nucleic acids themselves, or the polypeptides encoded by the nucleic acids of the

microarray, to retain any specific biological activity. Rather, the nucleic acids must be capable of hybridizing to an appropriate test nucleic acid when applied to the microarray. To draw this distinction, i.e., that the nucleic acid fragments need not either be themselves functional, nor encode functional proteins, amended claim 1 recites that the nucleic acid molecules of the claimed microarray encode polypeptides of complex I, II, III, IV, or V of the mitochondrial respiratory chain, or are fragments of such nucleic acid molecules, which are hybridizable array elements. The enablement and written description rejections on this basis are thus moot and may be withdrawn.

The Office further rejects the claims as encompassing sequences which are undetermined, i.e., that a gene name or GenBank number is insufficient to adequately identify the genes of the array. The basis for this rejection is respectfully traversed. As detailed in the previous reply filed November 30, 2006, identifying a known class of genes merely by class name, much less the particular gene names or GenBank numbers, is sufficient to identify the sequences for purposes of the written description and enablement requirements (see *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 79 U.S.P.Q.2d 1001 (Fed. Cir. 2006)). As in *Falkner*, Applicants are not claiming the nucleic acid sequences themselves. Here, the microarrays of the invention include nucleic acids that encode polypeptides of the mitochondrial complexes, or fragments of such nucleic acids. Specifically, the polypeptides are encoded by nuclear (rather than mitochondrial) genes. Thus, the identification of the gene class, along with identification of specific exemplary

genes of this class (see, e.g., Figure 1), is more than sufficient to describe and enable the use of these genes in the context of a microarray. The written description and enablement rejections on this basis may also be withdrawn.

In the August 9, 2007 interview, the Office further asked whether one of skill in the art would know what genes are encompassed by the term "nuclear encoded mitochondrial energy metabolism gene." Applicants submit that one of skill in the art would indeed know which genes are encompassed by this term. Mitochondrial energy metabolism genes are part of the electron transport chain, specifically the mitochondrial complexes I, II, III, IV, and V, which mediate electron transport and ATP production (energy metabolism). While Applicants submit the term "nuclear encoded mitochondrial energy metabolism gene" is clear, claim 1 has nonetheless been amended to recite "polypeptides of complex I, II, III, IV, or V of the mitochondrial respiratory chain." As the proteins of these complexes are well known in the art, the skilled artisan would accordingly know what nucleic acids are encompassed by the claimed microarrays.

Finally, the Office asserts that the claims broadly encompass a large number of variants, mutants, and homologues of the genes. Applicants respectfully disagree. Claim 1 provides for microarrays containing nucleic acids which encode polypeptides of the mitochondrial complexes, or fragments of such nucleic acids which are hybridizable array elements. The claims do not recite the variants, mutants, or homologues referred to by the

Office. For all of these reasons, the written description and enablement rejections may be withdrawn.

Rejection under 35 U.S.C. § 102(b)

The Office rejects claims 1 and 2 as anticipated by the Genome Array, asserting that this microarray includes all limitations of these claims. Applicants respectfully disagree. Claims 1 and 2 both require that the nucleic acids encode polypeptides of the mitochondrial complexes, or fragments thereof, and that these nucleic acids make up 90% of the nucleic acids on the claimed microarray. Applicants do not dispute that the Genome Array cited by the Office contains mitochondrial energy metabolism genes. Rather, of the 12,000 genes contained on the Genome Array, only a small fraction, and certainly fewer than 90%, are related to mitochondrial energy metabolism. Thus, the Genome Array does not meet all limitations of claim 1, 2, or 39-41, and thus cannot anticipate these claims.

In the August 9, 2007 interview, the Office asserted that the use of "comprising" in claim 1 would encompass the Genome Array, despite the recitation of 90% of the nucleic acid molecules on the support being mitochondrial energy metabolism nucleic acid molecules in the claim. Applicants respectfully disagree. The recitation of the 90% limitation would necessarily exclude the Genome Array from the scope of claims, 1, 2, and 39. Nonetheless, claim 1 has been amended to recite a microarray consisting of a

solid support and an array of at least two nucleic acid molecules bound to the support, where 90% of the nucleic acid molecules on the array are nucleic acid molecules encoding polypeptides of the mitochondrial complexes, or fragments thereof. Accordingly, claim 1, as amended, and dependent claims 2 and 39-41 are likewise not anticipated by the Genome Array. This rejection may therefore be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the final Office action for three (3) months, to and including September 5, 2007, and a check in payment of the required extension fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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